BICYCLIST AND ENVIRONMENTAL FACTORS ASSOCIATED WITH FATAL BICYCLE-RELATED TRAUMA IN ONTARIO

Brian H. Rowe, MD, MSc, CCFP (EM); Alison M. Rowe, BA; Gary W. Bota, MD, FRCPC

Objective: To identify bicyclist and environmental factors associated with fatal bicycle-related trauma in Ontario.

Design: Retrospective study.

Setting: Ontario.

Participants: Information was extracted from the provincial coroner's reports on 212 people who had died of bicycle-related injuries in Ontario between 1986 and 1991.

Outcome measures: Age, sex and helmet use of the bicyclist, time and place of the event, type of bicyclist or motorist error(s) and use of alcohol by bicyclist or motorist.

Results: Only 32% of the deaths involved bicyclists under 15 years of age. The male-female ratio was 3.5. Over 75% of the cases involved head injury, however, only 8 (4%) of the bicyclists had been wearing a helmet. In 91% of the cases death occurred as the result of a bicycle-motor vehicle collision. Most (65%) of the deaths for which the time was known occurred between 4 pm and 8 am. Bicyclist error was the main cause of crash for 26 (79%) of the children less than 10 years old, it was also the main cause of crash among the bicyclists aged 10 to 19 years (43 [55%]) and those aged 45 years or more (15 [44%]). However, motorist error was the most common cause of collision in the group of cyclists 20 to 44 years of age (42 [63%]). Alcohol was detected in the blood of 7% of the bicyclists killed, alcohol had been consumed by 30% of the motorists who claimed not to have seen the cyclist.

Conclusions: Bicycle-related deaths result from factors that are generally avoidable. Identifiable risk factors other than lack of helmet use suggest that additional research is required to determine the benefits of preventive interventions aimed at reducing the number of such deaths. Age-specific strategies appear warranted.

Objectif: Définir les aspects du cyclisme et de l'environnement qui sont liés à des traumatismes mortels subis par des cyclistes en Ontario.

Conception : Étude rétrospective.

Contexte: Ontario.

Participants: On a tiré des renseignements des rapports du coroner provincial sur 212 personnes décédées à la suite de blessures causées par un accident de bicyclette en Ontario entre 1986 et 1991.

Mesures des résultats : Âge et sexe du cycliste, port du casque, date, heure et lieu de l'accident, type d'erreurs commises par le cycliste ou par l'automobiliste et consommation d'alcool par le cycliste ou par l'automobiliste

Résultats: 32 % seulement des victimes avaient moins de 15 ans. Le ratio hommes-femmes était de 3,5. Plus de 75 % des victimes ont subi une blessure à la tête, mais 8 (4 %) des cyclistes seulement portaient un casque. Dans 91 % des cas, la mort a été causée par une collision entre une bicyclette et un véhicule à moteur. La plupart (65 %) des décès dont on connaît l'heure se sont produits entre 16 h et 8 h. Une erreur du cycliste a été la principale cause de 26 (79 %) des collisions chez les enfants de moins de 10

Dr. Rowe is research director of the Northeastern Ontario Family Medicine Program and the Sudbury General Hospital Lead Trauma Program, Sudbury, Ont. Ms. Rowe was research assistant with the Sudbury General Hospital Lead Trauma Program, Sudbury, Ont. Dr. Bota is director of the Emergency Department and the Lead Trauma Program, Sudbury General Hospital, Sudbury, Ont.

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Reprint requests to: Dr. Brian H. Rowe, Northeastern Ontario Family Medicine Program, Health Sciences Education Resource Centre, Laurentian University, Sudbury, ON P3E 2C6

ans, et la principale cause de collision chez les cyclistes de 10 à 19 ans (43 [55 %]) et chez ceux de 45 ans ou plus (15 [44 %]). L'erreur de l'automobiliste a toutefois été la cause la plus fréquente de collision chez les cyclistes de 20 à 44 ans (42 [63 %]). On a constaté la présence d'alcool dans le sang de 7 % des cyclistes tués, et 30 % des automobilistes qui ont affirmé ne pas avoir vu le cycliste avaient consommé de l'alcool.

Conclusions: Les causes d'accidents mortels chez les cyclistes sont en général évitables. Les facteurs de risque identifiables, outre l'absence du casque, indiquent que des recherches supplémentaires s'imposent si l'on veut déterminer les avantages d'interventions préventives qui visent à réduire le nombre de ces décès. Des stratégies axées sur l'âge semblent justifiées.

In North America bicycling is a recreational activity enjoyed by people of all ages. Its popularity is extensive. For example, it is estimated that more than 90% of children under the age of 10 own a bike and ride regularly. Recently, this interest in bicycling has resurfaced in adults as a means of transportation and a form of exercise. Associated with this increased use of bicycles has been a corresponding increase in nonintentional crashes resulting in injury. Each year in the United States more than 200 minor injuries per 100 000 bicyclists are estimated to occur. In addition, bicycle-related injuries have the potential to be severe (85 per 100 000 bicyclists each year) and occasionally fatal (2 per 100 000 bicyclists each year).

Serious injury from bicycle crashes appears to be multifactorial. First, bicyclists often share transportation routes with motorists, and this results in potentially serious collisions. Second, bicycles offer very little protection to the rider, and few bicyclists use protective equipment such as helmets. Third, the kinetic energy or speed attained by bicyclists may be quite impressive and may lead to severe injuries when crashes occur. Finally, adverse road conditions (e.g., pot holes, sewer grates and areas of construction) and environmental conditions that make it difficult to see bicyclists (e.g., nighttime driving and rain) may create a setting for trauma and injury.

Riders falling from bicycles suffer head injuries more often than limb and spinal trauma.² Severe head injury is a common cause of death. This may be why the most aggressive injury prevention strategies concentrate on promoting helmet use. Current estimates indicate that helmet use would be expected to reduce the risk of head injury by 85% and brain injury by 88%.^{15 to} Despite widespread support for helmet use over the past two decades, resistance exists and compliance is low.^{17 20} Community strategies may improve compliance with helmet use;^{20 21} however, legislation has been shown to increase helmet use most drastically.²² At present Manitoba is the only province with partial helmet legislation, although Ontario has recently passed legislation for universal bicycle helmet use, scheduled to take effect in October 1995.²³

Measures other than increasing helmet use may be required to reduce the number of serious and fatal bicycle-related injuries. For example, it has been suggested that wearing a helmet is a marker of safer cycling behaviour, and some of the reported protection credited to helmets may be the result of less severe injuries.²⁴ Consequently, even if helmet use increases, serious and fatal injuries will

likely remain a health care problem. Therefore, a more thorough evaluation of serious cycling-related injuries should be encouraged.

Despite their important contributions, studies of bicycle-related injuries usually do not specifically examine fatal events. First Bicycle-related deaths occur in previously healthy people and result in an important increase in the number of years of productive life lost. The value of examining such fatal events lies in their potential to provide insight into the extremes of trauma risk. The features of these events may help to identify areas in which preventive strategies may be used.

Little is known about the causes of bicycle crashes that result in death, particularly in different age groups. Several studies have assessed cause on the basis of injury reports; however, only one has carefully examined crash characteristics. Clarity has not emerged from these studies, and a more comprehensive system to classify the causes of fatal bicycle-related crashes is required if valid recommendations are to emerge.

In trauma epidemiology, factors relating to the environment, the vector or vehicle, and the operator's behaviour must be considered when examining causes.²⁵ However, mechanical problems do not appear to be common issues in bicycle-related trauma.⁵ Therefore, we undertook a study of cyclist and environmental factors associated with fatal bicycle-related trauma in Ontario. For environmental factors we included interactions or collisions with other road users, such as motor vehicles.

There were several objectives of this study: (a) to describe the demographic information and the characteristics of the fatal events and injuries, (b) to identify the causes of death of the cyclists and (c) to classify the type of crash by age group in order to identify factors of potential importance for prevention.

METHODS

We used a retrospective case-series approach to identify bicyclists who died of bicycle-related trauma from 1986 to 1991. Permission to examine the records was obtained under the Freedom of Information Act through the coroner's office

Under the Coroner's Act all trauma-related and sudden, unexplained deaths in Ontario must be reported to the chief coroner.²⁶ These deaths are assigned a code designating the environmental factors and the factors surrounding

the death. The environmental factors refer to the location of the activity that led to the death and are divided into a number of subgroups. For our study we used the subheading "recreation and sporting." We included all deaths related to bicycling (code 528) in this subgroup. To include incorrectly classified deaths we also examined the events listed in the subgroup "recreation (other)."

The factors surrounding the death refer to the action, force, instrument or disease occurring in an environment that led directly to the death. For example, a bicyclist may have drowned, fallen or collided with a motor vehicle. We did not exclude any charts on the basis of death factor alone. This classification system is unique to the Ontario coroner's office.

Information about the bicyclist and the event was available in the coroner's file from a variety of sources. Regional coroner's reports, police accident reports, autopsy findings and newspaper articles were included to varying degrees in each file. The police accident report provided the most complete data, and efforts were made to recover any of these missing reports from the appropriate police forces. Most charts contained more than one data source.

We included only trauma-related deaths that occurred as the result of bicycling. We excluded deaths unrelated to bicycling and those for which there were no obvious signs of trauma identified. Final decisions to include or exclude were made on the basis of the summary report provided by the regional coroner assigned to each case.

All charts were examined, and a checklist was completed for eligible cases only. Data included demographic characteristics of the patient (age, sex, place of residence), description of the event (e.g., location, type of road, weather conditions, time of day), causes (e.g., alcohol involvement, lack of bicycle helmet) and outcome (e.g., injury severity, time of death, autopsy results).

Patients were grouped by age (less than 10 years, 10 to 19, 20 to 44, and 45 and over) and cause of crash.^{27,28} Two reviewers independently judged cause of crash using the following three categories: bicyclist error, motorist error and unknown or other. Appendix 1 provides brief explanations of causes in each category.

Data were analysed using the Statview SE+ statistical software program (Abacus Inc., Calabasas, Calif.). Categoric values are reported as counts and percentages and were compared using the χ^2 test. Continuous variables are reported as means and standard deviations (SDs).

RESULTS

Records of 219 bicycle-related and 27 "other recreational" deaths were identified from the Coroner's Information System, all of the charts were located and examined. Of the 219 cases 211 met the inclusion criteria for bicycle-related deaths, the remaining 8 were classified as motorcycle-related death (2 cases), cerebrovascular accident (1), non-bicycle-related fall (1), motorized tricycle (wheelchair)

(1), congestive heart failure (1), death outside Ontario (1) and duplicate patient record (1). Of the 27 cases of "other recreational" death 1 involved bicycle use and was added to the series.

All but 2 of the 212 bicyclists in the study were operators of the bicycle; one death involved a passenger and the other a pedestrian. The peak year for bicycle-related deaths in Ontario was 1988 (51 [24%]). In other years approximately 30 to 35 deaths occurred. The number of deaths was distributed equally across the days of the week. Fig. 1 shows the frequency of deaths over the study period for each of the eight regions in Ontario. Bicycle-related deaths occurred most frequently in the Niagara and Southwestern regions.

Descriptive details of the people involved in the fatal crashes are summarized in Table 1. More males than females were involved; this difference did not vary with age. The mean age was 26.0 (SD 19.7) years (range 3 to 87 years). One third of the cases involved people less than 15 years of age.

Most of the deaths (146 [69%]) occurred during daylight hours (8 am to 8 pm); however, an important number (31 [15%]) occurred between midnight and 8 am (Table 2). Adverse weather conditions apparently played a small role in the 212 deaths. Although poor visibility due to precipitation intuitively may be an important factor, most of the deaths occurred during times of clear weather, when people are more likely to go bicycling.

The people suffered a variety of injuries that resulted in death, 75% of them had head injuries. Most (143 [67%]) died at the scene or in the emergency department, and only 24 (11%) survived 48 hours or more in hospital.

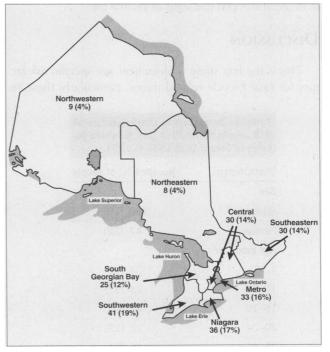


Fig. 1: Distribution of 212 fatal events of bicycle-related trauma in Ontario from 1986 to 1991 by region in which event occurred.

In all, 193 (91%) of the events were collisions with motor vehicles (Table 2). Such events were responsible for all the deaths involving children less than 10 years of age and for 88% of the deaths involving those 10 to 19. In the remaining age groups such events were only slightly less common (84% among those 20 to 44 years and 79% among those 45 or older).

Only 8 (4%) of the people were known to be wearing a helmet at the time of death. Helmet use was highest among those 20 to 44 years (Table 3). Bicyclist error was determined to be the main cause of the crash in 98 (66%) of the cases, and motorist error was determined to be the main cause in 87 (41%); in the rest of the cases cause was unclear.

Table 4 gives information on the types of error involved in the crashes. Among the people less than 10 years of age riding out onto the street midblock (midblock rideout) was more common than other types of error. Sudden turning or swerving into the path of a motor vehicle was the most common type of error among those 10 to 19 years. Of the 101 in the older groups failure of a motorist to detect the cyclist (in 43 [43%] of the cases) and falls (in 18 [18%]) were the leading causes. The cause of the falls could not be clearly determined in many of the cases. Only 7% of the bicyclists were intoxicated (7%) (Table 3).

Most of the crashes that resulted from motorist error involved the people in the older groups (those 20 years of age and over). For example, 64% of the older bicyclists, as compared with 36% of the younger ones, were killed by motorists who failed to detect them (Table 4). Failure to detect cyclists was more common during times of suboptimal lighting. Of all the motor vehicle—bicycle collisions 14% of the motorists had signs of alcohol use; 30% of those who failed to detect the cyclist had signs of alcohol use.

Discussion

This is the first study to document age-specific risk factors for fatal bicycle-related injury, particularly those in-

212 people who	e 1: Demographic characteristics of people who died of bicycle-related in- s in Ontario from 1986 to 1991				
Characteristic	No. (and %	s) of people			
Sex					
Male	165	(78)			
Female	47	(22)			
Age group, yr					
< 10	33	(16)			
10-14	35	(17)			
15–19	43	(20)			
20–24	22	(10)			
25-44	45	(21)			
≥ 45	34	(16)			

volving motor vehicle–bicycle collisions. Most of the deaths involved young adult males, and less than one third were of children under the age of 15 years. Contrary to some reports of fatal bicycle-related injuries that focused on children, we found a distribution of deaths across all age groups in Ontario. Participation in this sport is clearly not confined to children. Consequently, measures to prevent serious injury and death need to address the adult population as well.

Most (91%) of the deaths resulted from collisions between motor vehicles and bicycles. Age did play an important role in the crash characteristics. For example, very young children (those less than 10 years) were hit by motor vehicles most frequently in midblock rideouts. Such crashes commonly occur at the end of a driveway and represent a particularly preventable trauma.^{27,28}

Bicyclists 10 to 19 years of age were killed most frequently as they swerved or turned in front of a vehicle (Table 4). This may be the result of poorly developed peripheral vision or lack of attention and illustrates the tendency of bicyclists in this age group to ride on roads more often than younger children.

Finally, the biggest threat to the adult cyclist appears to be motorists' failure to detect them (Table 4). Fatal events

Table 2: Descriptive features of the	ble 2: Descriptive features of the fatal bicycle crashes				
Feature	No. (and %) of crashes				
Time of crash					
0801–1600	72 (34)				
1601–2000	74 (35)				
2001–2400	27 (13)				
0001–0800	31 (15)				
Unknown	8 (4)				
Day of crash					
Friday	30 (14)				
Saturday	32 (15)				
Sunday	36 (17)				
Other	114 (54)				
Mechanism					
Collided with a motor vehicle	193 (91)				
Fell or was thrown	12 (6)				
Collided with a fixed object	2 (1)				
Other	5 (2)				
Time of death					
Died at scene	84 (40)				
Died in emergency department	59 (28)				
Died in hospital < 48 h	43 (20)				
Died in hospital ≥ 48 h	24 (11)				
Missing data	2 (1)				

more commonly occurred at night and on busier roads among the adult bicyclists than among the younger bicyclists. This difference may reflect a number of issues. First, motorists often are still unprepared for the cyclist on the road. Second, cyclists continue to be difficult to see, often lacking headlights and reflective clothing when riding at night. Finally, the risk of alcohol impairment in motorists is greater at night, and such impairment affects vision and the ability to react to a changing environment.

Analysis of the results indicates that most of the deaths were preventable. Unfortunately, because of our rudimentary understanding of risk factors associated with fatal bicycle-related trauma, countermeasures or preventive interventions have been limited to the promotion of bicycle helmet use. In addition, most of the potential interventions have yet to be subjected to adequate scientific testing.

On the basis of our results we believe that strategies for reducing the incidence of serious and fatal bicycle-related injuries need to be targeted to separate age groups.

• Children less than 10 years old: Children in this age group are killed most often as a result of midblock rideouts. Since it has been shown that young children have

difficulty interpreting road signs and understanding rules of the road^{29,30} parental education and supervision are needed.³¹ Specifically, an intervention such as temporary barriers at the end of driveways when young children are cycling may be worth examining. This intervention has been suggested as a strategy to reduce the incidence of driveway-related trauma in other recreational activities such as sledding.³²

- Youths 11 to 19 years: In this age group bicycling errors are common.³³ This finding provides some merit for recommending that young cyclists complete training courses and obtain a license before being allowed to ride in traffic. Although this approach has yet to be formally studied, the concept has intuitive appeal and may better prepare the school-aged child for riding on roads. Some support the theory that children over the age of 10 may be better able than younger children to understand laws governing them, especially while cycling near traffic.³⁰ Further studies are required to assess the benefit of the training approach.
- Adults: Deaths in this age group occurred frequently at night. Other data support these observations and suggest

	Age group, yr; no. (and %) of people									
Factor	bib W	< 10	10)–19	20	0-44	Move 2	≥ 45	All	
Bicyclist	CONTRACTOR OF THE PARTY OF THE	- IIII								
Sex										
Male	21	(64)	66	(85)	49	(73)	29	(85)	165	(78)
Female	12	(36)	12	(15)	18	(27)	5	(15)	47	(22)
Helmet use										
Yes	1	(3)	1	(1)	6	(9)	0		8	(4)
No	32	(97)	77	(99)	61	(91)	34	(100)	204	(96)
Alcohol use										
Yes	0		2	(3)	12	(18)	2	(6)	16	(8)
No	33	(100)	76	(97)	55	(82)	32	(94)	196	(92
Environmental										
Time of crash										
0801-1600	13	(39)	25	(32)	16	(24)	18	(53)	72	(34
1601–2000	19	(58)	30	(38)	16	(24)	9	(26)	74	(35
2001–2400	0		13	(17)	12	(18)	2	(6)	27	(13
0001-0800	0		9	(12)	20	(30)	2	(6)	31	(15
Unknown	1	(3)	1	(1)	3	(4)	3	(9)	8	(4
Time of week*										
Weekday	21	(64)	44	(56)	37	(55)	22	(65)	124	(58
Weekend	12	(36)	33	(42)	28	(42)	9	(26)	82	(39
Alcohol use (motorist)										
Yes	2	(6)	10	(13)	13	(19)	5	(15)	30	(14
No	31	(94)	68	(87)	54	(81)	29	(85)	182	(86

that the risk of bicycle-related death is four times greater at night than at other times during the day. ^{11,14} Similar results have been seen in other forms of recreational injuries. ³⁴ These results highlight the need for bicyclists to minimize nighttime riding or improve their visibility through the use of lights and reflective clothing. ³⁵

• Motorists: Cases in which motorists failed to detect bicyclists were common, especially at night and on weekends, when alcohol use by motorists is more frequent. In the cases of failing to detect the cyclist 30% of the motorists had been drinking alcohol before the crash. Incorporation of bicycle awareness into driver training programs may help to reduce the incidence of all motor vehicle-bicycle collisions, especially those involving adult bicyclists; however, there is still little evidence available to substantiate this concept. In addition, it would appear that separation of bicycles and motor vehicles has merit. Unfortunately the data to support this are unclear.³⁶ In California, separation of bicycles and motor vehicles reduced the incidence of bicycle-car collisions by 31%.37 However, a Swedish study revealed that although the number of crashes was reduced, the severity of injuries from crashes on paths and roads was unchanged.³⁸ Designated bicycle paths, temporary road closures and the use of trails represent alternatives that warrant consideration in areas where bicycling is popular. 39,40

Many of the deaths in our study involved some form of head injury, 75% of the deaths directly resulting from such injury. Despite evidence to support the protective effect of

bicycle helmets, our results revealed a minimal increase in helmet use over the past decade.8 Continued efforts and pending legislation may increase helmet use, and future studies will determine the effectiveness of such programs. Finally, despite helmet use, many bicyclists continue to wear them improperly (i.e., poor placement or fit). Thus, potential benefits from the use of helmets (efficacy) may be less than expected (effectiveness).41

No study is complete without examining its strengths, weaknesses and generalizability of its results. We endeavoured to collect all cases of fatal bicycle-related trauma over a period for which the coroner's records were available. However, cases may have been missed. Only one bicycle-related death had been incorrectly classified in the category "recreation (other)," and eight deaths had been classified as bicycle related when, in fact, they were not. Finally, experience tells us that the coroner's records are quite complete and accurate. This study is one of the largest of its kind in the literature, and it is unlikely that sufficient cases escaped our attention to invalidate the results.

A potential problem exists with respect to the completeness of information sources for each case. For example, forensic alcohol tests had not been done in all of the cases. In addition, some of the files had missing reports. However, we believe that the data were generally comprehensive, almost all of the files having provided more than one data source. If bias did exist, we feel that there would have been an underestimation of some causal factors such as alcohol use.

Type of error	Age group, yr; no. (and %) of people							
	< 10	10-19	2	20-44	45	- 1	AII	
Bicyclist					La caracteria			
Rides onto street midblock	14 (54)	8 (31)	1	(4)	3 (12)	26	(12	
Rides through intersection	4 (17)	9 (38)	3	(12)	8 (33)	24	(11	
Turns or swerves into path of motor vehicle	8 (18)	26 (58)	7	(16)	4 (9)	45	(21	
Collides with motor vehicle while overtaking another bicycle or motor vehicle	0	0	3	(100)	0	3	(1	
Motorist								
Fails to detect bicyclist	5 (7)	19 (28)	33	(49)	10 (15)	67	(32)	
Turns into path of bicyclist	1 (12)	3 (38)	3	(38)	1 (12)	8	(4)	
Fails to stop at intersection	1 (25)	1 (25)	2	(50)	0	4	(2)	
Strikes bicyclist while overtaking another motor vehicle	0	3 (38)	4	(50)	1 (12)	8	(4)	
Unknown/other								
Bicyclist falls from bicycle or crashes with object other than motor vehicle; cause unclear	0	9 (33)	11	(41)	7 (26)	27	(13)	
Total	33 (16)	78 (37)	67	(32)	34 (16)	212	(100)	

Finally, we did not include cases of nonfatal bicyclerelated trauma. The value of examining fatal events lies in their potential to provide some insight into the extremes of trauma risk. The features of these events have helped to identify appropriate injury prevention priorities. It is logical and efficient to begin the categorization of age-specific causes with fatal events; however, future studies are required to validate these results and test these theories in nonfatal events.

Bicycling can and should be a safe recreational endeavour. Strategies outlined in this study may result in safer cycling, without the tragedy of traumatic injury and death.

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Appendix 1: Classification of causes of bicycle crashes^{27,28}

Bicyclist error

Rides onto street midblock: Bicyclist enters the road from a driveway or sidewalk suddenly; time for reaction of motorist is minimal.

Rides through intersection or exit lane: Bicyclist rides through an intersection or exit lane against traffic laws (either through a stop sign or red light); time for corrective action by bicyclist or motorist is minimal.

Turns or swerves into path of motor vehicle: Motorist is obeying traffic laws, but bicyclist suddenly turns or swerves into the path of the vehicle for whatever reason (e.g., turning across lanes, into a driveway or onto another road). Bicyclist apparently did not detect the motorist from behind or in oncoming lane.

Collides with motor vehicle while overtaking another bicycle or motor vehicle: Bicyclist overtakes either another bicycle or a motor vehicle and collides with an oncoming vehicle.

Motorist error

Fails to detect bicyclist: Bicyclist is obeying laws, but motorist does not detect bicyclist before collision. Pertains to all cases in which motorist strikes bicyclist that do not occur at an intersection and are not due to motorist turning or overtaking another vehicle.

Turns into path of bicyclist: Bicyclist is riding on the road (or shoulder or sidewalk), and motorist turns into his or her path; minimal time for the bicyclist to avoid the collision.

Fails to stop at intersection or exit lane: Bicyclist is not at fault; motorist collides with bicyclist who is crossing the street (e.g., at a crosswalk).

Strikes bicyclist while overtaking another vehicle: Motorist does not detect bicyclist and strikes the bicycle while pulling out of a lane to pass or into a lane after passing another vehicle.

Unknown/ other

Bicyclist falls from bicycle or collides with object other than a motor vehicle: Bicyclist falls from the bicycle, is thrown from the bicycle or has a collision with an object other than a motor vehicle. Error cannot be clearly determined.

thromboplastin reagents and provide additional guidance for defining the appropriate therapeutic regimen. Initial Dosage - The administration of COUMADIN dosing must be individualized according to the patient's sensitivity to the drug as indicated by the PT and/or INR. COUMADIN therapy is commonly started above anticipated maintenance dosage levels. A commonly used regimen for COUMADIN is 10 mg/day for 2 to 4 days, with daily dosage adjustments based on the results of PT/INR determinations. Use of a large loading dose may increase the incidence of haemorrhagic and other complications, does not offer more rapid protection against thrombi formation, and is not recommended.5 Lower initiation doses are recommended for elderly and/or debilitated patients and patients with increased sensitivity. (see PRECAUTIONS). Maintenance - Most patients are satisfactorily maintained at a dose of 2 to 10 mg daily. Flexibility of dosage is provided by breaking scored tablets in half. The individual dose and interval should be gauged by the patient's prothrombin response. Duration of therapy - The duration of therapy in each patient should be individualized. In general anticoagulant therapy should be continued until the danger of thrombosis and embolism has passed. LABORATORY CONTROL - The PT reflects the depression of vitamin K dependent Factors VII, IX, X and II. There are several modifications of the one-stage PT and the physician should become familiar with the specific method used in the laboratory. The degree of anticoagulation indicated by any range of PTs may be altered by the type of thromboplastin used; the appropriate therapeutic range must be based on the experience of each laboratory. The PT should be determined daily after the administration of the initial dose until PT results stabilize in the therapeutic range. Intervals between subsequent PT determinations should be based upon the physician's judgement of the patient's reliability and response to COUMADIN in order to maintain the individual within the therapeutic range. Acceptable intervals for PT determinations are normally within the range of one to four weeks. To ensure adequate control, it is recommended that additional PT tests are done when other warfarin products are interchanged with COUMADIN. TREATMENT DURING
DENTISTRY AND SURGERY - The management of patients who undergo dental and surgical procedures requires close liaison between attending physicians, surgeons and dentists. In patients who must be anticoagulated prior to, during, or immediately following dental or surgical procedures,

adjusting the dosage of COUMADIN to maintain the PT at the low end of the therapeutic range, may safely allow for continued anticoagulation. The operative site should be sufficiently limited and accessible to permit the effective use of local procedures for hæmostasis. Under these conditions, dental and surgical procedures may be performed without undue risk of hæmorrhage. CONVERSION FROM HEPARIN THERAPY - Since the onset of warlarins effect is delayed, heparin is preferred initially for rapid anticoagulation. Conversion to COUMADIN may begin concomitantly with heparin therapy or may be delayed 3 to 6 days. As heparin may affect the PT, patients receiving both heparin and COUMADIN should have blood drawn or PT determination, at least: 5 hours after last IV bolus dose of heparin, or 4 hours after cessation of a continuous IV infusion of heparin, or 24 hours after last subcutaneous heparin injection. When COUMADIN has produced the desired therapeutic range or prothrombin activity, heparin may be discontinued.

AVAILABILITY OF DOSAGE FORMS: COUMADIN (warfarin sodium) tablets are single-scored and imprinted as follows:

Strength	Imprint Side 1	Imprint Side 2	Colour	
1.0 mg	COUMADIN 1	Du Pont	Pink	
2.0 mg	COUMADIN 2	Du Pont	Lavender	
2.5 mg	COUMADIN 2.5	Du Pont	Green	
4.0 mg	COUMADIN 4	Du Pont	Blue	
5.0 mg	COUMADIN 5	Du Pont	Peach	
10.0 ma	COUMADIN 10	Du Pont	White	

Supplied in bottles of 100

Stability and Storage Recommendations: Protect from light. Store in carton until contents have been used. Store at controlled room temperature (15°C to 30°C). Dispense in a tight, light-resistant container as defined in the U.S.P.

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Complete prescribing information available upon request.

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DuPont Pharma 2655 North Sheridan Way Mississauga, Ontario L5K 2P8

